

# Module 1: SAFE - EFFECTIVE

Confident Parents – Intelligent Leaders – Articulate Activists

## Part 1. Are Vaccines Safe?

### Key points:

- A true placebo is not given to the control group in a safety study; it is considered “unethical”
- A second vaccine is often used as a placebo, now called a “comparator”
- If participants leave the trial for any reason, the final analysis is performed on those remaining, skewing the results by eliminating those with side effects
- Studies include only healthy children, even though a vaccine is recommended for all children after it is approved
- NO studies have been done to prove vaccine safety.

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### ASSUMPTIONS BEHIND VACCINATION PRACTICES

1. Vaccines are safe
2. Vaccines are effective – i.e. they protect you from getting sick
3. Vaccines are the most significant public health advances of the 21<sup>st</sup> century
4. All vaccines should be mandatory for all

Webster’s Dictionary defines “safe” as:

- Giving protection
- Trustworthy
- Involving no risk
- Unable to cause trouble or damage

### Problem #1: No placebo is used in safety studies

“As a general rule, research subjects in the control group of a clinical trial of ***should receive an established, effective intervention.*** In some circumstances, it ***may be*** ethically acceptable to use a placebo or “no treatment.”

“Using a **placebo** in the control arm would **deprive subjects** of an established effective intervention... therefore it would be unethical to use a placebo.”

- **REFERENCE:** International Ethical Guidelines for Epidemiological Studies Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the WHO, February, 2008. page 56-57
- When is Using a Placebo “appropriate?”
- **2002:** Guidelines for when a “placebo” may be used in a vaccine trial:
  - An approved vaccine for the same illness is not available
  - When withholding an approved vaccine would expose the control group to an illness unnecessarily

- When the use of an established vaccine as comparator would not yield scientifically reliable results
- When the use of a placebo would not cause any risk of serious or irreversible harm to the subjects.

**Problem #2: The control group is given another vaccine or a vaccine ingredient for comparison of side effects**

- The 'placebo' can be **another vaccine**, called a comparator
  - When Pediarix was brought to market:
  - Pediarix = DTaP + polio + Hep B in one combo shot
  - "Placebo" = DTaP + polio + Hep B given as separate shots
  - **EXAMPLE: EnergixB**

"Ten double-blind studies involving 2,252 subjects showed no significant difference in the frequency or severity of adverse experiences between ENGERIX-B and Hepatitis B plasma-derived vaccines...All subjects were monitored for 4 days post-administration."

    - **REFERENCE: ENGERIX-B package insert**
- The 'placebo' can be an injection of a **vaccine ingredient**
  - **Example: Gardasil** had 250 mcg of aluminum.
    - **An injection of aluminum** was used as the 'placebo' in the 'safety study' for the Gardasil 4 vaccine, given to young girls and boys in an attempt to prevent cervical and rectal cancer.
    - When the side effects of a Gardasil vaccine were comparable to the side effects of a 250 mcg injection of aluminum, investigators call Gardasil "as safe as placebo."
  - **EXAMPLE: Gardasil**
    - The vaccine was tested on fewer than 12,000 girls aged 9-12 years, subjects were followed for only 6 months. Normally, drugs are followed for 4 years before they are approved
      - Observation for adverse events: **15 days**
    - Each Gardasil dose contains 225 mcg of aluminum
    - 25.4% - injection site pain and swelling after receiving Gardasil
    - 15.8% - injection site pain and swelling after receiving the shot of aluminum (i.e. the placebo).
- The 'placebo' can be an '**add-on**'
  - *Subjects are given either **the trial vaccine** mixed with an existing vaccine Or **the trial vaccine** mixed with something considered to be inert, such as a placebo.*
    - **REFERENCE: EXPERT CONSULTATION ON THE USE OF PLACEBOS IN VACCINE TRIALS. WORLD HEALTH ORGANIZATION, 2013. Geneva, Switzerland. Pg. 13**

**Problem #3: In vaccine trials, negative side effects can be eliminated with a stroke of a pen**

- If a participant experiences a side effect after any dose, s/he is dropped from the trial.

- The data analysis is done on the number of participants remaining in the trial. Therefore, the conclusions are skewed toward positive results and negative consequences – including serious side effects - are ignored.

**Problem #4:** Studies include only healthy children

- Children with chronic illnesses, seizure disorders, other medical conditions are excluded, *even though the vaccine is recommended – or required – for all children once the vaccine is approved.*
- **Example:** The Prevnar7 safety study
  - **Healthy infants** were randomized 1:1 to receive either the Prevnar conjugate vaccine or the Men type C vaccine at 2, 4, 6 and 12 to 15 months of age.
  - Children with sickle cell disease, known immunodeficiency, **any serious chronic or progressive disease**, a history of seizures or a history of either pneumococcal or meningococcal disease **were excluded.**
    - **REFERENCE:** Black, Steven, et al. "The safety and immunogenicity of heptavalent pneumococcal conjugate vaccine in children." *Pediatr Infect Dis J*, 2000;19:187-95 Vol. 19, No. 3

**Summary: The Problem with Safety Studies**

- **Problem #1:** A true placebo is not given to the control group in a safety study; it is considered "unethical"
- **Problem #2:** A second vaccine is often used as a placebo, now called a "comparator"
- **Problem #3:** If participants leave the trial for any reason, the final analysis is performed on those remaining, skewing the results by eliminating those with side effects
- **Problem #4:** Studies include only healthy children, even though a vaccine is recommended for all children after it is approved

**Additional Take-Aways:**

1. **NO studies have been done to prove vaccine safety.**
  - In fact, the U.S. Supreme Court has said that vaccines are "unavoidably unsafe."
2. The one-size-fits-all vaccination schedule is dangerous and, IMO, and a fraud.
  - Every vaccine has different ingredients and every human being has a different genetic constitution.
  - Therefore, **every vaccination is an experiment** and can lead to unpredictable results, including serious side effects and even death.

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